

Appl. No. 10/615,651

Amdt. dated JANUARY 23, 2006

Reply to Final Office Action of September 21, 2005

### REMARKS

Applicant has received and carefully reviewed the Final Office Action mailed on September 21, 2005, as well as the advisory action mailed on December 12, 2005. Claims 1-11, 13-14, and 35-39 are pending, with claim 14 withdrawn from consideration, claims 15-34 cancelled without prejudice, and claims 35-39 newly presented. Reconsideration and reexamination are respectfully requested.

On page 2 of the Final Office Action, claim 1 was rejected under 35 U.S.C. §102(b) as being anticipated by Stevens, EP 0841072. After careful review of the cited reference, Applicant respectfully disagrees.

Claim 1 recites:

1. A method of forming a catheter, comprising:
  - providing a braid layer having a distal end and a proximal end, an inner lubricious liner positioned within the braid layer;
  - securing a first polymer segment over the braid layer, the first polymer segment being positioned proximal of the distal end of the braid layer, the first polymer segment having a distal end and a proximal end;
  - cutting through the braid layer and the inner lubricious liner at a cutting position proximate the distal end of the first polymer segment and removing a portion of the braid layer that extends distally of the cutting position; and
  - securing a second polymer segment over the braid layer, the second polymer segment extending over the first polymer segment and extending distally of the cutting position.

Applicant notes that claim 1 recites securing a first polymer segment over the braid layer. The segment that is being secured has proximal and distal ends. Therefore, it is a separate piece apart from other parts of the catheter prior to being secured thereto. However, Stevens illustrates coextruding a braid coating over the braid and elastomeric inner member. In particular, Stevens notes several problems with other methods at column 8, lines 24-41. Stevens states:

It is important that only enough epoxy or other adhesives be applied to fill the interstices of the wire braid and onto the base coating. This is hard to control using coatings. In the preferred form according to the present invention therefore, the coating for bonding the braid to the body tube is extruded onto the entire length of the feedstock carrying the elastomeric body tube with the braided overlay.

(Stevens at column 8, lines 33-41). From the above, Stevens considers the coextrusion of the braid coating to be an important step. However, this is contrary to that which is recited in claim

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1. Therefore, Stevens does not anticipate claim 1, at least because Stevens does not disclose securing a first polymer segment over the braid layer, the first polymer segment being positioned proximal of the distal end of the braid layer, the first polymer segment having a distal end and a proximal end, as recited in claim 1. It is believed that the §102(b) rejection of claim 1 is therefore overcome.

On pages 3-6, claims 2-5, 7, 9-11 and 13 were rejected under 35 U.S.C. §103(a) as being unpatentable over Stevens in view of U.S. Patent No. 5,951,929 to Wilson.

As explained above, Stevens does not illustrate the step of securing a first polymer segment over the braid layer, the first polymer segment being positioned proximal of the distal end of the braid layer, the first polymer segment having a distal end and a proximal end, as set forth in claim 1. While this aspect of the claim is not specifically addressed in the obviousness rejection, it is believed that a modification to include a separate first polymer segment, rather than use of coextrusion, would be non-obvious.

Specifically, in Stevens, the use of coextrusion, rather than placement of a separate member over the shaft, appears to be performed at least in part due to the sheer length of the mandrel/shaft being used. For example, Stevens suggests "a continuous reel of five thousand (5,000) feet of mandrel feedstock. (Stevens at column 7, lines 54-55). This long length is cut into individual catheter lengths after the reinforcing wire layer has been ground off at a number of selected locations, as Stevens sets forth in column 9. It is not apparent to Applicant how or why one would modify Stevens to make use of a separate member over the shaft on the braid, particularly given Stevens' emphasis on the use of coextrusion as an improvement, and given that Stevens starts with more than  $\frac{3}{4}$  of a mile of mandrel.

Wilson suggests a method of forming a catheter having overlapping welds. Much of the disclosure, including, for examples, Figures 6-10, is directed to such overlapping welds. Applicant cannot see the relevance of this portion of Wilson to the present claims. Wilson also discusses an embodiment shown in Figures 13-14 for attaching a distal tip. Within this embodiment, Wilson discusses separately preparing and cutting the braid for use in the catheter. (Wilson at column 7, lines 33-44.) A distal portion of the braid is annealed such that it lies flat on the inner member. Then:

In order to facilitate loading of the axial jacket sections over the intermediate braided tube layer 122, it has also been found desirable to anchor the end of the

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wire braid layer or tube 122 to the Teflon® layer 120 to further facilitate loading the axial jacket sections. In a preferred arrangement in accordance with the process of this invention, the annealed end of the wire braid layer or tube 122 is anchored to the inner Teflon® layer 120 using a small, thin walled (0.002 inch) sleeve 126 of PEBA material. After the sleeve 126 is loaded onto the annealed end of the braided tube as shown in FIG. 13, a first shrink film or tube 128 is applied over the sleeve. The shrink film, which may be formed of FEP-Teflon®, is then heated to 385°-400° F. so that the compressive force during shrinking, combined with the heat inherent in the process, causes the PEBA sleeve 126 to melt into the interstices of the braided layer 122, at the same time that the cut end wires are being forced flat against the Teflon® layer 120. This results in the end wires being held neatly in place so that they will not be disturbed during the remainder of the assembly process.

(Wilson, at column 7, line 57 through column 8, line 9). Figure 13 illustrates that the distal ends of the braid 122 and the sleeve 126 are aligned:

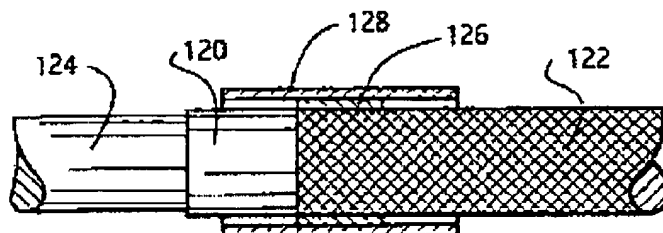


FIG.13

As such, Wilson also does not suggest securing a first polymer segment over the braid layer, the first polymer segment being positioned proximal of the distal end of the braid layer, the first polymer segment having a distal end and a proximal end, as recited in claim 1.

The Examiner cites Wilson in the various rejections of claims 2-5, 7, 9-11 and 13 to show polymer melting point differences (claim 2), the use of shrink tubes (claims 3-4), specific melting points (claim 5), particular materials (claims 7, 9, and 10), and multiple sections for the second member (claim 11). It appears that only Stevens is cited against claim 13. None of these citations of Wilson remedies the problems with the original rejection of claim 1, and therefore, the Examiner has not met the burden of a *prima facie* case of obviousness. Further, in light of the teachings of Stevens, Applicant does not believe that modification of the disclosed coextrusion would be appropriate, and even if it were, the combination does not show each and every element of the claim.

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In light of the above, Applicant believes claim 1 is patentable over the cited combination of Stevens in view of Wilson. This is so because Stevens teaches away from substitution of placement of a separate inner member for the disclosed coextrusion, and also because neither reference teaches an element of the present invention. In view of the patentability of claim 1 over the cited combination, Applicant believes that the Examiner has not met the requirements of a *prima facie* case of obviousness for claims 2-5, 7, 9-11 and 13.

On page 6 of the Office Action, claim 6 was rejected as being obvious in light of Stevens and Wilson in view of U.S. Patent App. Pub. No. 2004/0015150 to Zadno-Azizi. It appears that Zadno-Azizi is cited merely to illustrate material properties of a certain polymer, and not to address any of the above noted problems with the Stevens-Wilson rejection. Applicant again believes that the Examiner has not stated a *prima facie* case of obviousness of either claim 1 or dependent claim 6, and each is believed to be patentable over the cited combination.

On pages 6-7 of the Office Action, claim 8 was rejected as being obvious in light of Stevens in view of Ashiya et al., U.S. Patent No. 5,947,925. As before, Ashiya et al. is cited merely to illustrate the use of a particular polymer, and not to address any of the above noted problems with the Stevens rejection as applied against claim 1. Therefore, Applicant again believes that the Examiner has not stated a *prima facie* case of unpatentability of either claim 1 or dependent claim 8, meaning each is believed to be patentable over the cited combination.

In light of the above, it is believed that claim 1 is allowable. Claim 1 is generic over claim 14. Therefore, examination of dependent claim 14 is respectfully requested.

Applicants have also added new claims 35-39. Newly presented independent claim 35 recites a method of forming a catheter comprising cutting a catheter sub-assembly at a cutting location, the sub-assembly having proximal and distal ends, an inner layer, a reinforcement layer disposed on the inner layer, and a securement layer disposed over at least a portion of the reinforcement layer, removing the inner layer, the reinforcement layer, and the securement layer distally of the cutting location, and securing a polymeric outer segment over at least the securement layer such that a portion of the polymeric outer segment extends distally past the distal end of the cut sub-assembly. Claim 36 depends from claim 35 and recites that the method further comprises forming a portion of the polymeric outer segment into a distal tip for the catheter.

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Claim 37 also depends from claim 35 and recites that the method further comprises assembling the catheter sub-assembly by providing an inner sub-assembly having the reinforcement layer disposed on the inner layer, and disposing the securement layer on the inner sub-assembly by securing a securement segment thereon. Claim 38 depends from claim 37 and adds that the reinforcement layer has a distal end, the securement segment has a distal end, and the step of disposing the securement layer on the inner sub-assembly is performed such that the distal end of the reinforcement layer extends distally beyond the distal end of the securement segment. Claim 39 depends from claim 35 and recites that the reinforcement layer comprises a braided member.

Applicant respectfully requests examination and allowance of new claims 35-39.

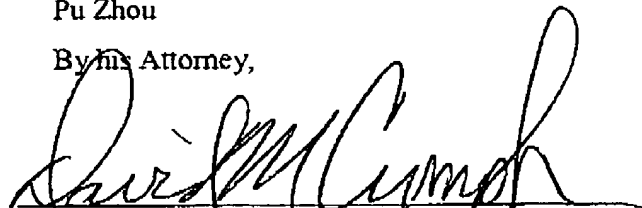
Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Pu Zhou

By his Attorney,

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